(1) *Combinations of skin protectant and external analgesic active ingredients in §347.20(b).* In addition to any or all of the indications for skin protectant drug products in §347.50(b)(1), any or all of the allowable indications for external analgesic drug products may be used if the product is labeled for concurrent symptoms.

(2) *Combinations of skin protectant and first aid antiseptic active ingredients in §347.20(c).* In addition to any or all of the indications for skin protectant drug products in §347.50(b)(1), the required indications for first aid antiseptic drug products should be used.

(3) *Combinations of skin protectant and sunscreen active ingredients in §347.20(d).* In addition to any or all of the indications for skin protectant drug products in §347.50(b)(2)(i), the required indications for sunscreen drug products should be used and any or all of the additional indications for sunscreen drug products may be used.

(c) *Warnings.* The labeling of the product states, under the heading ''Warnings,'' the warning(s) for each ingredient in the combination, as established in the warnings section of the applicable OTC drug monographs unless otherwise stated in this paragraph (c).

(1) *For combinations containing a skin protectant and a sunscreen identified in §§347.20(d) and 352.20(b).* The warnings for sunscreen drug products in §352.60(c) of this chapter are used.

(2) [Reserved]

(d) *Directions.* The labeling of the product states, under the heading ''Directions,'' directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (d). When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

(1) *For combinations containing a skin protectant and a sunscreen identified in §§347.20(d) and 352.20(b).* The directions for sunscreen drug products in §352.60(d) of this chapter are used.

(2) [Reserved]

PART 348—EXTERNAL ANALGESIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

Subpart B—Active Ingredients

Subpart C—Labeling

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 57 FR 27656, June 19, 1992, unless otherwise noted.

Subpart A—General Provisions

§348.1 Scope.

(a) An over-the-counter external analgesic drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in §330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§348.3 Definitions.

As used in this part:

(a) *Male genital desensitizing drug product.* A drug product applied to the penis to help in temporarily slowing the onset of ejaculation.

(b) [Reserved]